

109TH CONGRESS
1ST SESSION

S. 2104

To amend the Public Health Service Act to establish the American Center for Cures to accelerate the development of public and private research efforts towards tools and therapies for human diseases with the goal of early disease detection, prevention, and cure, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 14, 2005

Mr. REID (for Mr. LIEBERMAN (for himself, Mr. COCHRAN, Mr. CARPER, and Mrs. HUTCHISON)) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to establish the American Center for Cures to accelerate the development of public and private research efforts towards tools and therapies for human diseases with the goal of early disease detection, prevention, and cure, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “American Center for
5 Cures Act of 2005”.

1 SEC. 2. TABLE OF CONTENTS.

2 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Findings.
- Sec. 4. American Center for Cures.

“PART J—AMERICAN CENTER FOR CURES

- “Sec. 499A. Definitions.
- “Sec. 499B. Establishment of American Center for Cures.

“SUBPART 1—FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS

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“SUBPART 3—CLINICAL TRIALS

- “Sec. 499E. Increasing research study participation.
- “Sec. 499E–1. Grants for quality clinical trial design and execution.
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- “Sec. 499E–4. Clinical research study and clinical trial.
- “Sec. 499E–5. Authorization of appropriations.

“SUBPART 4—VALLEY OF DEATH

- “Sec. 499F. Small business partnerships.
- “Sec. 499F–1. Rapid access to intervention development.
- “Sec. 499F–2. Toxicity studies.
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“SUBPART 5—OFFICE OF TECHNOLOGY TRANSFER

- “Sec. 499G. Restructuring.
- “Sec. 499G–1. Marketing function.
- “Sec. 499G–2. Office of Intramural Risk Opportunity and Mapping.
- “Sec. 499G–3. Patenting and licensing incentives.
- “Sec. 499G–4. Translational researcher development.
- “Sec. 499G–5. Translational research training program.

“SUBPART 6—DEVELOPING INFORMATION SYSTEMS

- “Sec. 499H. Advancing national health information infrastructure.
- “Sec. 499H–1. Public access requirement for research.
- “Sec. 499H–2. Informatics training and workforce development.
- “Sec. 499H–3. National Library of Medicine expansion of facilities.

“SUBPART 7—RESEARCH TOOLS

- “Sec. 499I. NIH research tool inventory.
- “Sec. 499I–1. Exceptions to tool guidelines.

1 **SEC. 3. FINDINGS.**

2 Congress finds the following:

3 (1) The National Institutes of Health (referred
4 to in this section as the “NIH”) is the United
5 States premier biomedical research investment with
6 annual appropriations exceeding \$28,000,000,000.

7 (2) The mission of the NIH is science in pur-
8 suit of fundamental knowledge about the nature and
9 behavior of living systems and the application of
10 that knowledge to extend healthy life and reduce the
11 burdens of illness and disability.

12 (3) The pace of knowledge application to pro-
13 mote health and reduce disease can be influenced
14 through strategic funding and reorganization of
15 some aspects of the traditional research endeavor.
16 This process is known as translational research in-
17 vestment.

18 (4) The United States translational research in-
19 vestment will be key to the Nation responding effec-
20 tively—

21 (A) to acute man-made or natural health
22 threats;

23 (B) to the complexity and multi-discipli-
24 nary nature of chronic diseases, which are re-
25 sponsible for 7 out of every 10 deaths in the
26 United States and for more than 70 percent of

1 the \$1,700,000,000,000 spent in the United
 2 States on health care each year; and

3 (C) to research and development vacuums
 4 in the private for-profit market, such as in the
 5 fields of vaccine and antibiotic production,
 6 drugs for Third World diseases, and medical
 7 tools for pediatric populations.

8 (5) Key components of the translational re-
 9 search process include research prioritization, an ex-
 10 pert workforce, multi-disciplinary collaborative work,
 11 facilitated information exchange, strategic risk tak-
 12 ing, support of small innovative businesses caught
 13 along common pathways in the research and devel-
 14 opment Valley of Death, simplification and pro-
 15 motion of the clinical research endeavor, and involve-
 16 ment of private entities early on in the translational
 17 research endeavor that are skilled in the manufac-
 18 turing and marketing process.

19 **SEC. 4. AMERICAN CENTER FOR CURES.**

20 (a) AMERICAN CENTER FOR CURES.—Title IV of the
 21 Public Health Service Act (42 U.S.C. 281 et seq.) is
 22 amended by adding at the end the following:

23 **“PART J—AMERICAN CENTER FOR CURES**

24 **“SEC. 499A. DEFINITIONS.**

25 “In this part:

1 “(1) CENTER.—The term ‘Center’ means the
2 American Center for Cures established under section
3 499B.

4 “(2) COUNCIL.—The term ‘Council’ means the
5 Cures Council established under section 499B.

6 “(3) DIRECTOR.—The term ‘Director’ means
7 the Director of the American Center for Cures.

8 “(4) INCUBATOR.—The term ‘incubator’ means
9 an economic development organization designed to
10 accelerate the growth and success of entrepreneurial
11 individuals, concepts, and companies.

12 “(5) RESEARCH TOOL.—The term ‘research
13 tool’ means a resource that scientists use in their
14 laboratories that has no immediate therapeutic or di-
15 agnostic value, including cell lines, monoclonal anti-
16 bodies, reagents, laboratory equipment and ma-
17 chines, databases, and computer software.

18 “(6) TEST BED.—The term ‘test bed’ means
19 the pilot environment to prototype innovation.

20 “(7) TRANSLATIONAL RESEARCH.—The term
21 ‘translational research’ means investigation in which
22 knowledge obtained from fundamental research such
23 as with genes, cells, or animals, is transformed
24 through early and late stage development proto-
25 typing and testing into diagnostic or therapeutic

1 interventions that can be applied to the treatment or
2 prevention of disease or frailty.

3 **“SEC. 499B. ESTABLISHMENT OF AMERICAN CENTER FOR**
4 **CURES.**

5 “(a) IN GENERAL.—There is established within the
6 National Institutes of Health an American Center for
7 Cures—

8 “(1) whose mission shall be to increase the ca-
9 pacity of the National Institutes of Health to pro-
10 mote translational research, including between the
11 institutes and centers of the National Institutes of
12 Health, between the National Institutes of Health
13 and other Federal agencies, and between grantees
14 and business partners of the National Institutes of
15 Health, so as to speed the development of effective
16 therapies, diagnostics, and cures essential to human
17 health and well being;

18 “(2) that shall formulate and implement a
19 strategy for the Nation’s translational research in-
20 vestment, which strategy shall include—

21 “(A) a prioritization of biomedical research
22 on diseases based on disease burden and re-
23 search promise; and

24 “(B) funding for innovative, multidisci-
25 plinary, and collaborative research across the

1 institutes and centers of the National Institutes
2 of Health, across Federal agencies, and between
3 public and private partners of the National In-
4 stitutes of Health;

5 “(3) that shall be guided, in part, by a series
6 of ‘Grand Challenges’ formulated through collabora-
7 tion between the Director of Cures and the Council,
8 that shall be strategic challenges that direct the pub-
9 lic and private health research community towards
10 collaborative multi-staged projects that have the po-
11 tential to transform the healthcare environment,
12 such as—

13 “(A) the creation of laboratory diagnostics
14 that enable the Nation to detect quickly and ac-
15 curately acute health threats such as an avian
16 flu pandemic or a bioterrorism attack;

17 “(B) a focus on therapeutic delivery sys-
18 tems targeting individual viruses or hard to
19 reach cells in the body, such as the brain, using
20 advances in nanotechnology;

21 “(C) accelerated research into the potential
22 of stem cells to replace the form and function
23 of tissues lost to patients suffering from dis-
24 eases such as spinal cord injury, Parkinson’s
25 disease, and insulin-dependent diabetes;

1 “(D) creation of a biomedical informatics
2 infrastructure that can organize the human ge-
3 nome and the proteins for which the genome
4 codes in ways that scientists can better under-
5 stand the genetic contribution to phenotypic
6 disease;

7 “(E) the elaboration of adjuvant tech-
8 nology that can bolster the effectiveness of vac-
9 cines;

10 “(F) development of antigen sparing vac-
11 cines such as those based on triggering the in-
12 nate immune response;

13 “(G) development of rapid vaccine manu-
14 facturing capacity from new production meth-
15 ods such as viral cell culture or bioengineering
16 technology;

17 “(H) creation of a fast track clinical trial
18 infrastructure that incorporates a national doc-
19 tor and patient registry, centralized investiga-
20 tional review boards, electronic medical records,
21 and other health information technologies;

22 “(I) a focus on addressing less profitable
23 conditions for which research and development
24 efforts are insufficient, such as—

1 “(i) orphan, small population, and
2 third world diseases;

3 “(ii) antibiotic resistance;

4 “(iii) a threat of a flu epidemic or
5 pandemic;

6 “(iv) diseases associated with social
7 stigma such as depression and seizure dis-
8 orders; or

9 “(v) other comparable problems;

10 “(J) a commitment by researchers and
11 manufacturers from all sectors to develop vac-
12 cines for the world’s most deadly infectious dis-
13 eases, including HIV, tuberculosis, and malaria;
14 and

15 “(K) other appropriate challenges; and

16 “(4) that shall have other appropriate purposes.

17 “(b) DIRECTOR OF THE CENTER AND THE DIRECTOR
18 OF NIH.—

19 “(1) IN GENERAL.—The Center shall be admin-
20 istered by a Director of Cures who shall be ap-
21 pointed by the President with the advice and consent
22 of the Senate. The Director of the NIH, in consulta-
23 tion with the Council, shall recommend candidates
24 for the Director of Cures to the President.

25 “(2) ACTIVITIES.—

1 “(A) DIRECTOR OF NIH.—The Director of
2 NIH shall—

3 “(i) work with the Director of Cures
4 to promote translational research efforts;
5 and

6 “(ii) serve as a co-chair of the Coun-
7 cil.

8 “(B) DIRECTOR OF CURES.—

9 “(i) ACCELERATION FUND.—

10 “(I) IN GENERAL.—The Director
11 of Cures shall have at the Director’s
12 disposal an annual acceleration fund
13 to provide support for research and
14 development of breakthrough bio-
15 medical discoveries and to carry out
16 the purpose of the Center. Amounts in
17 the fund may be available through
18 grants, contracts, and cooperative
19 agreements to public sector entities,
20 private sector entities, and non-gov-
21 ernmental organizations. The Director
22 of Cures shall allocate not less than
23 ½ of the acceleration funds to the
24 Health Advanced Research Projects
25 Agency described in subpart 2. The

1 remainder of such funds shall be
2 available to the Federally Funded Re-
3 search and Development Centers de-
4 scribed in subpart 1 and other activi-
5 ties of the Center.

6 “(II) AUTHORIZATION OF APPRO-
7 PRIATIONS.—There are authorized to
8 be appropriated to fund the accelera-
9 tion fund under subclause (I)
10 \$5,000,000,000 for fiscal year 2007
11 and each succeeding fiscal year.

12 “(ii) DIRECT OTHER OFFICES.—The
13 Director of Cures shall direct other offices
14 within the Center that are established
15 under this part.

16 “(c) COUNCIL.—

17 “(1) ESTABLISHMENT.—There is established
18 within the Center a Cures Council that shall convene
19 not less frequently than twice a year to help advise
20 and direct the translational research efforts of the
21 Center.

22 “(2) MEMBERSHIP.—

23 “(A) IN GENERAL.—The Council shall be
24 composed of the following members:

1 “(i) The Director of NIH and the Di-
2 rector of Cures who shall be Council co-
3 chairs.

4 “(ii) The heads of the institutes and
5 centers of the National Institutes of
6 Health.

7 “(iii) Heads from not less than 9 Fed-
8 eral agencies, including—

9 “(I) the Administrator for the
10 Substance Abuse and Mental Health
11 Services Administration;

12 “(II) the Under Secretary for
13 Science and Technology of the De-
14 partment of Homeland Security;

15 “(III) the Commanding General
16 for the United States Army Medical
17 Research and Materiel Command;

18 “(IV) the Director of the Centers
19 for Disease Control and Prevention;

20 “(V) the Commissioner of Food
21 and Drugs;

22 “(VI) the Director of the Office
23 of Science of the Department of En-
24 ergy;

1 “(VII) the President of the Insti-
2 tute of Medicine;

3 “(VIII) the Director of the Agen-
4 cy for Healthcare Research and Qual-
5 ity; and

6 “(IX) the Director of the Defense
7 Advanced Research Projects Agency.

8 “(B) OTHER MEMBERS.—Membership of
9 the Council shall also include not fewer than 3
10 leaders from the small business community, 3
11 leaders from large pharmaceutical or bio-
12 technology companies, and 3 leaders from aca-
13 demia, all of whom shall be appointed by the
14 President.

15 “(3) SUBCOMMITTEES.—The Council or the
16 Council co-chairs may form subcommittees of the
17 Council as needed.

18 “(4) RECOMMENDATIONS; COORDINATION.—
19 The Council shall make recommendations that help
20 the Director of Cures set research priorities for the
21 Center. In making recommendations, the Council
22 shall consider risk and burden of disease as well as
23 lines of research uniquely poised to deliver effective
24 diagnostics and therapies. The Council shall also co-
25 ordinate research priorities in, and ensure sharing of

1 research agendas among, the institutes and centers
2 of the National Institutes of Health.

3 “(5) OFFICE OF INTRAMURAL RISK OPPOR-
4 TUNITY AND MAPPING.—The Council shall be aided
5 by the Office of Intramural Risk Opportunity and
6 Mapping of the Office of Technology Transfer of the
7 Center established in subpart 5.

8 “(6) ANNUAL ASSESSMENT.—The Council shall
9 make an annual assessment of the priorities and
10 progress of the Center and shall make the assess-
11 ment available to the public in written and electronic
12 form.

13 “(d) BUDGET AND FUNDS.—The Director of Cures
14 shall—

15 “(1) prepare and submit, directly to the Presi-
16 dent for review and transmittal to Congress, an an-
17 nual budget estimate for the Center, after reason-
18 able opportunity for comment (but without change)
19 by the Secretary, the Director of NIH, and the
20 Council; and

21 “(2) receive from the President and the Office
22 of Management and Budget directly all funds appro-
23 priated by Congress for obligation and expenditure
24 by the Center.

1 **“Subpart 1—Federally Funded Research and**
 2 **Development Centers**

3 **“SEC. 499C. FEDERALLY FUNDED RESEARCH AND DEVEL-**
 4 **OPMENT CENTERS.**

5 “(a) IN GENERAL.—The Director of Cures is author-
 6 ized to establish 1 or more Federally Funded Research
 7 and Development Centers that shall carry out activities
 8 related to the mission of the Center, as described in sec-
 9 tion 499B(a)(1).

10 “(b) DUTIES.—

11 “(1) IN GENERAL.—The Federally Funded Re-
 12 search and Development Centers shall serve as sites
 13 for the performance of multidisciplinary and cross-
 14 disciplinary research and shall—

15 “(A) establish, as appropriate, technology
 16 test beds and incubators;

17 “(B) utilize cooperative agreements with
 18 the private sector; and

19 “(C) conduct large-scale multidisciplinary
 20 translational research projects in health or dis-
 21 ease areas that are essential to medical ad-
 22 vancement but lack adequate private sector
 23 funding.

24 “(2) CONSULTATION.—In carrying out the du-
 25 ties described in paragraph (1), the Federally Fund-
 26 ed Research and Development Centers shall consult

1 widely with representatives from private industry, in-
2 stitutions of higher education, nonprofit institutions,
3 other Federal governmental agencies, and other fed-
4 erally funded research and development centers.

5 “(c) COMPETITION.—The Director of Cures shall en-
6 sure that competitive mechanisms are used to select and
7 to promote the ongoing quality and performance of the
8 Federally Funded Research and Development Centers.

9 “(d) TERM OF FUNDING.—Federally Funded Re-
10 search and Development Centers shall be funded for not
11 more than 7 years, after which time the Federally Funded
12 Research and Development Centers’ re-funding shall be
13 contingent upon approval by the Director of Cures and
14 the Council.

15 “(e) REPORTS.—Each Federally Funded Research
16 and Development Center receiving funding under this sec-
17 tion shall submit a biannual report to the Director and
18 the appropriate committees of Congress on the activities
19 carried out by the Federally Funded Research and Devel-
20 opment Center under this section.

21 “(f) FUNDING FOR SUPPORT.—For any fiscal year,
22 the Director of Cures may use not more than 25 percent
23 of the funds available to the Director under the accelera-
24 tion fund under section 499B(b)(2)(B)(i)(II) to establish

1 Federally Funded Research and Development Centers
2 under this section.

3 **“Subpart 2—Health Advanced Research Projects**

4 **“SEC. 499D. HEALTH ADVANCED RESEARCH PROJECTS**
5 **AGENCY.**

6 “(a) ESTABLISHMENT.—There is established within
7 the Center a Health Advanced Research Projects Agency
8 (referred to in this section as the ‘Research Projects Agen-
9 cy’) that shall—

10 “(1) carry out activities related to the mission
11 of the Center, as described in section 499B(a)(1);
12 and

13 “(2) be headed by a Director of the Research
14 Projects Agency who is appointed by the Director of
15 Cures.

16 “(b) COMPOSITION.—The Research Projects Agency
17 shall be composed of not more than 100 portfolio man-
18 agers in key health areas, which areas are determined by
19 the Director of the Research Projects Agency in conjunc-
20 tion with the Director of Cures and the Council.

21 “(c) GUIDANCE.—The Research Projects Agency
22 shall be guided by and shall undertake grand challenges
23 formulated by the Center that encourage innovative,
24 multi-disciplinary, and collaborative research across insti-
25 tutes and centers of the National Institutes of Health,

1 across Federal agencies, and between public and private
2 partners of the National Institutes of Health.

3 “(d) MANAGEMENT GUIDANCE.—The Research
4 Projects Agency shall be guided by the following manage-
5 ment and organizing principles in directing the Research
6 Projects Agency:

7 “(1) Keep the Research Projects Agency small,
8 flexible, entrepreneurial, and non-hierarchical, and
9 empower portfolio managers with substantial auton-
10 omy to foster research opportunities with freedom
11 from bureaucratic impediments in administering the
12 manager’s portfolios.

13 “(2) Seek to employ the strongest scientific and
14 technical talent in the Nation in research fields in
15 which the Research Projects Agency is working.

16 “(3) Rotate a significant portion of the staff
17 after 3 to 5 years of experience to ensure continuous
18 entry of new talent into the Research Projects Agen-
19 cy.

20 “(4) Use whenever possible research and devel-
21 opment investments by the Research Projects Agen-
22 cy to leverage comparable matching investment and
23 coordinated research from other institutes and cen-
24 ters of the National Institutes of Health, from other

1 Federal agencies, and from the private and non-
2 profit research sectors.

3 “(5) Utilize supporting technical, contracting,
4 and administrative personnel from other institutes
5 and centers of the National Institutes of Health in
6 administering and implementing research effort to
7 encourage participation, collaboration, and cross-fer-
8 tilization of ideas across the National Institutes of
9 Health.

10 “(6) Utilize a challenge model in Research
11 Projects Agency research efforts, creating a
12 translational research model that supports funda-
13 mental research breakthroughs, early and late stage
14 applied development, prototyping, knowledge diffu-
15 sion, and technology deployment.

16 “(7) Establish metrics to evaluate research suc-
17 cess and periodically revisit ongoing research efforts
18 to carefully weigh new research opportunities
19 against ongoing research.

20 “(8) Tolerate risk-taking in research pursuits.

21 “(9) Ensure that revolutionary and break-
22 through technology research dominates the Research
23 Projects Agency’s research agenda and portfolio.

24 “(e) ACTIVITIES.—Using the funds and authorities
25 provided to the Director of Cures, and the authorities pro-

1 vided to the Director of NIH, the Research Projects Agen-
 2 cy shall carry out the following activities:

3 “(1) The Research Projects Agency shall sup-
 4 port basic and applied health research to promote
 5 revolutionary technology changes that promote
 6 health needs.

7 “(2) The Research Projects Agency shall ad-
 8 vance the development, testing, evaluation, proto-
 9 typing, and deployment of critical health products.

10 “(3) The Research Projects Agency, consistent
 11 with recommendations of the Council, with the prior-
 12 ities of the Director of Cures, and with the need to
 13 discuss challenges described in section 499B(a)(3),
 14 shall emphasize—

15 “(A) translational research efforts, includ-
 16 ing efforts conducted through collaboration with
 17 the private sector, that pursue—

18 “(i) innovative health products that
 19 could significantly and promptly address
 20 acute health threats such as a flu pan-
 21 demic, spread of antibiotic resistant hos-
 22 pital acquired infections, or other com-
 23 parable problems;

24 “(ii) remedies for diseases afflicting
 25 lesser developed countries;

1 “(iii) remedies for orphan and small
2 population diseases;

3 “(iv) alternative technologies with sig-
4 nificant health promise that are not well-
5 supported in the system of health research,
6 such as adjuvant technology or tech-
7 nologies for vaccines based on the innate
8 immunological response; and

9 “(v) fast track development, including
10 development through accelerated comple-
11 tion of animal and human clinical trials,
12 for emerging remedies for significant pub-
13 lic health problems; and

14 “(B) other appropriate translational re-
15 search efforts for critical health issues.

16 “(4) The Research Projects Agency shall utilize
17 funds to provide support to outstanding research
18 performers in all sectors and encourage cross-dis-
19 ciplinary research collaborations that will allow sci-
20 entists from fields such as information and computer
21 sciences, nanotechnology, chemistry, physics, and en-
22 gineering to work alongside top researchers with
23 more traditional biomedical backgrounds.

24 “(5) The Research Projects Agency shall pro-
25 vide selected research projects with single-year or

1 multi-year funding and require researchers for such
2 projects to provide interim progress reports to the
3 Research Projects Agency on not less frequently
4 than a biannual basis.

5 “(6) The Research Projects Agency shall award
6 competitive, merit-reviewed grants, cooperative
7 agreements, or contracts to public or private entities,
8 including businesses, federally-funded research and
9 development centers, and universities.

10 “(7) The Research Projects Agency shall pro-
11 vide advice to the Director of Cures concerning
12 funding priorities.

13 “(8) The Research Projects Agency may solicit
14 proposals for competitions to address specific health
15 vulnerabilities identified by the Director and award
16 prizes for successful outcomes.

17 “(9) The Research Projects Agency shall peri-
18 odically hold health research and technology dem-
19 onstrations to improve contact among researchers,
20 technology developers, vendors, and acquisition per-
21 sonnel.

22 “(10) The Research Projects Agency shall carry
23 out other activities determined appropriate by the
24 Director of Cures.

25 “(f) EMPLOYEES.—

1 “(1) HIRING.—The Research Projects Agency,
2 in hiring employees for positions with the Research
3 Projects Agency, shall have the same hiring and
4 management authorities as described in section 1101
5 of the Strom Thurmond National Defense Author-
6 ization Act for Fiscal Year 1999 (5 U.S.C. 3104
7 note).

8 “(2) TERM.—

9 “(A) IN GENERAL.—Except as provided in
10 subparagraph (B), the term of such appoint-
11 ments for employees of the Research Projects
12 Agency may not exceed 5 years.

13 “(B) EXTENSION.—The Director of the
14 Research Projects Agency may, in the case of
15 a particular employee of the Research Projects
16 Agency, extend the term to which employment
17 is limited under subparagraph (A) by up to 2
18 years if the Director of the Research Projects
19 Agency determines that such action is necessary
20 to promote the efficiency of the Research
21 Projects Agency.

22 “(g) FLEXIBILITY.—The Research Projects Agency
23 shall have the authority to flexibly fund projects, including
24 the prompt awarding, releasing, enhancing, or withdrawal

1 of monies in accordance with the assessment of the Re-
 2 search Projects Agency and project manager.

3 “(h) FUNDING.—The Research Projects Agency shall
 4 utilize funds received from the acceleration fund, described
 5 in section 499B(b)(2)(B)(i), for the Agency’s research and
 6 development activities. There is authorized to be appro-
 7 priated from such fund \$2,500,000,000 to carry out the
 8 activities of the Research Projects Agency.

9 **“Subpart 3—Clinical Trials**

10 **“SEC. 499E. INCREASING RESEARCH STUDY PARTICIPA-**
 11 **TION.**

12 “The Director of NIH shall establish a national clin-
 13 ical study registry within the National Library of Medicine
 14 of the National Institutes of Health in accordance with
 15 section 499H. The Center shall publicize the registry, with
 16 attention given to minority groups that are frequently
 17 underrepresented in clinical trials.

18 **“SEC. 499E-1. GRANTS FOR QUALITY CLINICAL TRIAL DE-**
 19 **SIGN AND EXECUTION.**

20 “The Director of Cures—

21 “(1) shall award grants for clinical trial design
 22 and execution to academic centers to fund multi-dis-
 23 ciplinary clinical research teams, which clinical re-
 24 search teams may be composed of members who in-

1 clude project managers, clinicians, epidemiologists,
2 social scientists, and nursing staff; and

3 “(2) may award grants for clinical trial design
4 and execution to researchers from small firms with
5 highly promising novel therapeutic entities.

6 **“SEC. 499E-2. STREAMLINING THE REGULATORY PROCESS**
7 **GOVERNING CLINICAL RESEARCH.**

8 “(a) ESTABLISHMENT OF CENTRALIZED INSTITU-
9 TIONAL REVIEW BOARDS.—

10 “(1) IN GENERAL.—The Director of Cures shall
11 establish a series of Centralized institutional Review
12 Boards (referred to in this section as ‘CIRBs’) to
13 serve as human subject safety and well being
14 custodians for multi-institutional clinical trials that
15 are funded partially or in full by public research dol-
16 lars.

17 “(2) EXISTING GUIDELINES AND BEST PRAC-
18 TICES.—CIRBs shall be established in accordance
19 with professional best practices and Good Clinical
20 Practice (GCP) guidelines so that institutions in-
21 volved in multi-institutional studies may—

22 “(A) use joint review;

23 “(B) rely upon the review of another quali-
24 fied institutional review board; or

1 “(C) use similar arrangements aimed to
2 avoid duplication of effort and to assure a high
3 quality of expert oversight.

4 “(b) HOUSED.—Each CIRB shall be housed—

5 “(1) at the institute or center of the National
6 Institutes of Health with expertise on the subject of
7 the clinical trial; or

8 “(2) at a public or private institution with com-
9 parable organizational capacity, such as the Depart-
10 ment of Veterans Affairs.

11 “(c) SERVICE.—The use of CIRBs shall be available,
12 as appropriate, at the request of public or private institu-
13 tions and shall be funded through user fees of the CIRBs
14 or the Center’s funds.

15 “(d) REVIEW PROCESS.—

16 “(1) IN GENERAL.—Each CIRB shall review re-
17 search protocols and informed consent to ensure the
18 protection and safety of research participants en-
19 rolled in multi-institutional clinical trials.

20 “(2) PROCESS.—The CIRB review process shall
21 consist of contractual agreements between the CIRB
22 and the study sites of multi-institutional clinical
23 trials. The CIRB shall act on behalf, in whole or in
24 part, of the bodies ordinarily responsible for the
25 safety of research subjects in a locality. In the case

1 in which a locality does not have such a body, the
2 locality shall depend solely on the CIRB to oversee
3 the protection of human subjects and the CIRB
4 shall assume responsibility for ensuring adequate as-
5 sessment of the local research context.

6 “(e) RESEARCH APPLICATIONS.—

7 “(1) IN GENERAL.—Each CIRB shall review
8 and package research applications for facilitated
9 electronic review by local institutional review boards
10 participating in a multi-institutional clinical trial.

11 “(2) LOCAL REVIEW.—Local institutional re-
12 view board review may be performed by a sub-
13 committee of the local institutional review board that
14 is empowered to make decisions in a timely manner.

15 “(3) CIRB REVIEW.—A local institutional re-
16 view board may accept or reject a CIRB review. In
17 the case in which a local institutional review board
18 accepts a CIRB review, the CIRB shall assume re-
19 sponsibility for annual, amendment, and adverse
20 event reviews.

21 “(f) WORK IN CONCERT.—In the case in which a
22 local institutional review board works in concert with a
23 CIRB, the local institutional review board shall be respon-
24 sible for taking into consideration local characteristics (in-
25 cluding ethnicity, educational level, and other demographic

1 characteristics) of the population from which research
2 subjects will be drawn, which influence, among other
3 things, whether there is sound selection of research sub-
4 jects or whether adequate provision is made to minimize
5 risks to vulnerable populations.

6 “(g) COMMUNICATION OF IMPORTANT INFORMA-
7 TION.—Each CIRB shall regularly communicate impor-
8 tant information in electronic form to the local institu-
9 tional review boards or, in cases where a local institutional
10 review board does not exist, to the principal investigator,
11 including regular safety updates or changes in research
12 protocol to improve safety.

13 “(h) COORDINATION.—Each CIRB shall fully coordi-
14 nate with the institute or center of the National Institutes
15 of Health that has specialized knowledge of the research
16 area of the clinical trial. Other Federal agencies and pri-
17 vate entities undertaking clinical trials may contract with
18 the Center to use a CIRB.

19 **“SEC. 499E-3. TRAINING CLINICAL RESEARCHERS OF THE**
20 **FUTURE.**

21 “The Center shall augment the National Institutes
22 of Health’s investment into programs dedicated to devel-
23 oping the clinical research workforce for tomorrow. The
24 programs shall include:

1 “(1) The National Institutes of Health’s
 2 Mentored Patient-Oriented Research Career Devel-
 3 opment Award to support the career development of
 4 investigators who have made a commitment to focus
 5 their research endeavors on patient-oriented re-
 6 search.

7 “(2) The National Institutes of Health’s award
 8 to encourage mentorship among particularly talented
 9 early- and mid-career investigators doing clinical re-
 10 search who want to train new investigators.

11 “(3) The National Institutes of Health grants
 12 to help institutions develop curricula for clinical re-
 13 searchers leading to a clinical science certificate or
 14 master’s degree.

15 “(4) The National Institutes of Health grants
 16 to fund participants in clinical science programs, in-
 17 cluding clinical science certificates or clinical science
 18 masters’ degrees.

19 **“SEC. 499E–4. CLINICAL RESEARCH STUDY AND CLINICAL**
 20 **TRIAL.**

21 “The Director of NIH shall—

22 “(1) commission the Institute of Medicine of
 23 the National Academies to study the rules that pro-
 24 tect patient safety and anonymity so that in a con-
 25 temporary clinical research context, a better balance

1 can be achieved between clinical research promotion
 2 and regulatory requirement governing research sub-
 3 ject safety and privacy; and

4 “(2) request that the Institute of Medicine issue
 5 a written report not later than 18 months after the
 6 date of enactment of this part that shall—

7 “(A) consider changes to the Health Insur-
 8 ance Portability and Accountability Act of 1996
 9 (Public Law 104–191) and the amendments
 10 made by such Act that further promote the
 11 clinical research endeavor; and

12 “(B) include recommendations for changes
 13 that shall not be limited to legislation but shall
 14 include changes to health care systems and to
 15 researcher practice that facilitate the clinical re-
 16 search endeavor.

17 **“SEC. 499E–5. AUTHORIZATION OF APPROPRIATIONS.**

18 “There are authorized to be appropriated from the
 19 acceleration fund of the Director of Cures described in sec-
 20 tion 499B(b)(2)(B)(i)—

21 “(1) \$100,000,000 to carry out section 499E–
 22 1(1) for fiscal year 2007 and each succeeding fiscal
 23 year;

24 “(2) \$50,000,000 to carry out section 499E–2
 25 for fiscal year 2007 and each succeeding fiscal year;

1 “(3) \$200,000,000 to carry out section 499E–
 2 3 for fiscal year 2007 and each succeeding fiscal
 3 year; and

4 “(4) \$2,500,000 to carry out section 499E–4.

5 **“Subpart 4—Valley of Death**

6 **“SEC. 499F. SMALL BUSINESS PARTNERSHIPS.**

7 “(a) ESTABLISHMENT OF THE OFFICE OF BIOSCI-
 8 ENTIFIC ENTERPRISE DEVELOPMENT.—

9 “(1) ESTABLISHMENT.—There is established
 10 within the Office of Technology Transfer of the Cen-
 11 ter (as established in subpart 5) an Office of Biosci-
 12 entific Enterprise Development (referred to in the
 13 subpart as the ‘OBED’).

14 “(2) TRANSFERS.—

15 “(A) IN GENERAL.—The OBED shall in-
 16 clude the functions (including related personnel
 17 and resources) of the following programs of the
 18 Office of Extramural Research in the Office of
 19 the Director of the National Institutes of
 20 Health:

21 “(i) The Small Business Innovation
 22 Research program (referred to in this sub-
 23 part as the ‘SBIR’).

1 “(ii) The Small Business Technology
2 Transfer program (referred to in this sub-
3 part as the ‘STTR’).

4 “(B) TIME FOR TRANSFERS.—The Sec-
5 retary shall ensure that the programs described
6 in subparagraph (A) are transferred to the
7 OBED not later than 6 months after the date
8 of enactment of this part.

9 “(b) SBIR AND STTR GRANTS AND CONTRACTS.—

10 “(1) IN GENERAL.—Not less than 35 percent of
11 the grants and contracts awarded by the SBIR and
12 STTR shall be awarded on a competitive basis by an
13 OBED program manager with sufficient managerial,
14 technical, and translational research expertise to
15 expertly assess the quality of a SBIR or STTR pro-
16 posal. The OBED, through such project manager,
17 shall place special emphasis on SBIR and STTR
18 grant and contract applications that identify from
19 the onset products with commercial potential that
20 influence human health.

21 “(2) POTENTIAL PURCHASERS OR INVES-
22 TORS.—The OBED shall administer non-peer re-
23 viewed grants and contracts under this subsection
24 through program managers who shall place special
25 emphasis on partnering grantees and entities award-

1 ed contracts from the very beginning of the research
 2 and development process with potential purchasers
 3 or investors of the products, including large pharma-
 4 ceutical or biotechnology companies, venture capital
 5 firms, and Federal agencies (including the National
 6 Institutes of Health).

7 “(3) PHASE I AND II.—The OBED shall reduce
 8 the time period between Phase I and Phase II fund-
 9 ing of grants and contracts under the SBIR and
 10 STTR to—

11 “(A) 6 months; or

12 “(B) less than 6 months if the grantee or
 13 entity awarded a contract demonstrates that
 14 the grantee or entity awarded a contract has in-
 15 terest from third parties to buy or fund the
 16 product developed with the grant or contract.

17 “(4) PHASE III.—

18 “(A) FUNDING.—A program manager
 19 under this subsection may petition the Director
 20 of Cures for Phase III funding of the grant or
 21 contract for a project that requires a boost to
 22 finalize procurement of a product. The max-
 23 imum funding for Phase III funding of a
 24 project shall be \$2,000,000 for a maximum of
 25 2 years. Such Phase III funding shall come

1 from the acceleration fund, as described in sec-
2 tion 499B(b)(2)(B)(i), of the Director of Cures.

3 “(B) REPORT SUCCESS.—Each recipient of
4 a SBIR or STTR grant or contract, as a condi-
5 tion of receiving such grant or contract, shall
6 report to the OBED whether there was even-
7 tual commercial success of the product devel-
8 oped with the assistance of the grant or con-
9 tract.

10 “(5) RECORD.—

11 “(A) IN GENERAL.—The OBED shall keep
12 a publicly accessible electronic record of all
13 SBIR or STTR investments in research and de-
14 velopment.

15 “(B) CONTENTS.—The record described in
16 subparagraph (A) shall include, at minimum,
17 the following information:

18 “(i) The grantee or entity awarded a
19 contract.

20 “(ii) A description of the research
21 being funded.

22 “(iii) The amount of money awarded
23 in each phase of SBIR or STTR funding.

24 “(iv) If applicable, the purchaser of
25 the product, current use of the product,

1 and estimated annual revenue resulting
2 from the procurement.

3 “(6) BONUS.—For each fiscal year, for the non-
4 peer reviewed SBIR and STTR grants or contracts,
5 the 2 program managers who are most successful in
6 terms of the number of grantees or entities awarded
7 a contract who complete Phase III shall each be
8 awarded a \$10,000 bonus.

9 **“SEC. 499F-1. RAPID ACCESS TO INTERVENTION DEVELOP-**
10 **MENT.**

11 “(a) ESTABLISHMENT OF OFFICE.—The Office of
12 Technology Transfer of the Center shall establish an Of-
13 fice of Rapid Access to Intervention Development (re-
14 ferred to in this subpart as the ‘RAID’) that—

15 “(1) is designed to assist translating promising,
16 novel, and scientifically meritorious therapeutic
17 interventions to clinical use by providing support to
18 help investigators navigate the product development
19 pipeline;

20 “(2) shall aim to remove barriers between lab-
21 oratory discoveries and clinical trials of new molec-
22 ular therapies, technologies, and other clinical inter-
23 ventions;

24 “(3) shall aim to progress, augment, and com-
25 plement the innovation and research conducted in

1 private entities to reduce duplicative and redundant
2 work using public funds; and

3 “(4) shall coordinate with the offices of the Na-
4 tional Institutes of Health that promote
5 translational research in the pre-clinical phase across
6 the National Institutes of Health.

7 “(b) PROJECTS.—

8 “(1) IN GENERAL.—The RAID, in collaboration
9 with the Director of Cures, shall carry out a pro-
10 gram that shall select, in accordance with paragraph
11 (2), projects of eligible entities that shall receive ac-
12 cess to laboratories, facilities, and other support re-
13 sources of the National Institutes of Health for the
14 pre-clinical development of drugs, biologics,
15 diagnostics, and devices.

16 “(2) SELECTION.—Not less than 35 percent of
17 the projects selected under paragraph (1) shall be
18 selected on a competitive basis by a program man-
19 ager with sufficient managerial, technical, and
20 translational research expertise to adequately assess
21 the quality of a project proposal. Projects under
22 paragraph (1) may also be selected from a peer re-
23 view process.

24 “(3) ELIGIBLE ENTITIES.—In this subsection,
25 the term ‘eligible entity’ means—

1 “(A) a university researcher;

2 “(B) a nonprofit research organization; or

3 “(C) a firm of less than 100 employees in
4 collaboration with 1 or more universities or
5 nonprofit organizations.

6 “(4) DISCONTINUE SUPPORT.—The RAID may
7 discontinue support of a project if the project fails
8 to meet commercialization success criteria estab-
9 lished by the RAID.

10 “(c) DISCOVERIES FROM LAB TO CLINIC.—The pro-
11 gram under subsection (b) shall accelerate the process of
12 bringing discoveries from the laboratory to the clinic
13 through—

14 “(1) the development of pharmacological assays;

15 “(2) the scale-up of production from lab scale
16 to clinical-trials scale;

17 “(3) the development of suitable formulations;

18 “(4) the evaluation of chemical stability;

19 “(5) the evaluation of materials testing for du-
20 rability or reactivity;

21 “(6) undertaking initial toxicology studies;

22 “(7) planning clinical trials; and

23 “(8) advice regarding the investigational new
24 drug or investigational new device filing with the
25 Food and Drug Administration.

1 “(d) ONGOING REVIEW.—The RAID shall review, on
2 an ongoing basis, potential products and may not support
3 products past the proof-of-principle stage.

4 **“SEC. 499F-2. TOXICITY STUDIES.**

5 “(a) ONGOING RESEARCH.—The Center shall sup-
6 port ongoing research into the most efficient methods of
7 screening for in vivo toxicity, including using cell-based
8 and animal model technologies.

9 “(b) OFFER OF STUDIES.—The Director of Cures
10 shall direct the Office of Technology Transfer of the Cen-
11 ter to offer toxicity studies as an available feature to pre-
12 ceed completion of licensing agreement contracts because
13 toxicity studies are expensive and rate-limiting barriers to
14 the licensing of intellectual property from the National In-
15 stitutes of Health.

16 "SEC. 499F-3. ADDITIONAL FUNDING SOURCES AND MOD-
17 ELS.

18 “The Director of Cures may provide acceleration
19 funds, described in section 499B(b)(2)(B)(i), for innova-
20 tive custom contracts for translational research develop-
21 ment to entities that license intellectual property from the
22 National Institutes of Health where such contracts sup-
23 port innovation and new models of cooperation and com-
24 mercialization.

1 **“SEC. 499F–4. AUTHORIZATION OF APPROPRIATIONS.**

2 “There are authorized to be appropriated from the
3 acceleration fund of the Director of Cures described in sec-
4 tion 499B(b)(2)(B)(i)—

5 “(1) \$400,000,000 to carry out section 499F
6 for fiscal year 2007 and each succeeding fiscal year;
7 and

8 “(2) \$100,000,000 to carry out section 499F–
9 1 for fiscal year 2007 and each succeeding fiscal
10 year.

11 **“Subpart 5—Office of Technology Transfer**

12 **“SEC. 499G. RESTRUCTURING.**

13 “(a) ESTABLISHMENT.—There is established within
14 the Center an Office of Technology Transfer (referred to
15 in this subpart as the ‘OTT’).

16 “(b) TRANSFERS.—The OTT shall include the func-
17 tions (and related personnel and resources) of the Office
18 of Technology Transfer in the Office of the Director of
19 the National Institutes of Health.

20 **“SEC. 499G–1. MARKETING FUNCTION.**

21 “(a) IN GENERAL.—The OTT shall establish a pro-
22 gram that—

23 “(1) cultivates industry interest in funded re-
24 search of the National Institutes of Health;

25 “(2) reaches out to potential industry partners;

1 “(3) coordinates patents from the other insti-
2 tutes and centers of the National Institutes of
3 Health; and

4 “(4) manages Cooperative Research and Devel-
5 opment Agreements, biological licensing agreements,
6 material transfer agreements, and intellectual prop-
7 erty licensing.

8 “(b) PROMOTION.—The program under subsection
9 (a) shall assist in promoting the success of government
10 and industry partnerships for the development of new
11 technologies by soliciting involvement of the private sector
12 from the beginning of the translational research process,
13 including by creating an electronic database within the
14 National Library of Medicine, which shall be updated reg-
15 ularly, that tabulates translational research efforts occur-
16 ring at the National Institutes of Health. The OTT shall
17 hold an annual national translational research conference
18 that brings together researchers and industry representa-
19 tives from across fields from both the private and public
20 sectors.

21 “(c) TRANSFER MANAGEMENT AND SUPPORT.—The
22 OTT shall develop a program for transfer management
23 and support that is familiar with the National Institutes
24 of Health’s intramural and extramural research portfolio,
25 which program’s mission is to reach out to potential indus-

1 try partners to cultivate interest in collaboration with pub-
 2 lic researchers with the goal of product development and
 3 procurement. For those Institutes or Centers with their
 4 own Office of Technology Transfer Offices, the OTT shall
 5 work closely with those offices to coordinate industry out-
 6 reach efforts. Those offices, on a biannual basis, shall
 7 meet with the OTT and shall submit a report to the OTT
 8 describing the translational research efforts of the Center
 9 or Institute and corresponding efforts to attract commer-
 10 cial interest in their research portfolio.

11 “(d) MANAGEMENT.—

12 “(1) IN GENERAL.—The OTT shall manage the
 13 Cooperative Research and Development Agreements
 14 between industry and public research partners.

15 “(2) REGISTRATION.—The OTT shall—

16 “(A) as appropriate, register the agree-
 17 ments within a publicly accessible electronic
 18 database maintained by the National Library of
 19 Medicine of the National Institutes of Health;
 20 and

21 “(B) oversee the collaborative process in
 22 terms of pre-determined outputs, negotiating
 23 problems that may occur between collaborating
 24 entities, and assuring intellectual property pro-

1 tections necessary for successful product devel-
2 opment.

3 **“SEC. 499G-2. OFFICE OF INTRAMURAL RISK OPPORTUNITY**
4 **AND MAPPING.**

5 “(a) ESTABLISHMENT.—There is established in the
6 Office of Technology Transfer of the Center, an Office of
7 Intramural Risk Opportunity and Mapping that shall
8 oversee the intramural research programs of the National
9 Institutes of Health to be certain they are complementary
10 and distinct from extramural and private programs.

11 “(b) REVIEWS AND REPORTS.—The Office of Intra-
12 mural Risk Opportunity and Mapping shall—

13 “(1) conduct regular reviews of the intramural
14 research programs of the National Institutes of
15 Health; and

16 “(2) report every 2 years on such reviews.

17 “(c) HEALTH RISKS AND OPPORTUNITIES.—The Of-
18 fice of Intramural Risk Opportunity and Mapping shall—

19 “(1) identify and map public health risks and
20 scientific opportunities and keep data on such topics
21 current and updated; and

22 “(2) provide the information described in para-
23 graph (1) to the Council on a biannual basis to help
24 the Council prioritize the Nation’s translation re-
25 search investment.

1 “(d) TRANS-NIH COLLABORATIVE RESEARCH.—

2 “(1) IN GENERAL.—The Office of Intramural
3 Risk Opportunity and Mapping shall make, in co-
4 ordination with the Director of Cures and the Direc-
5 tor of NIH, funds available to groups of institutes
6 and centers of the National Institutes of Health to
7 promote engagement in multi-institute projects that
8 focus on translational research endeavors.

9 “(2) FUNDING.—Funding levels and periods of
10 funding under paragraph (1) shall be flexible as nec-
11 essary to achieve trans-institute project objectives.
12 Preference for funding shall be given to projects that
13 promote high levels of cross-disciplinary collabora-
14 tion, that address diseases with the greatest burden
15 or research promise, and that are most likely to re-
16 sult in the development of a diagnostic or thera-
17 peutic prototype.

18 “(3) AUTHORIZATION OF APPROPRIATIONS.—
19 There is authorized to be appropriated, from the ac-
20 celeration fund of the Director of Cures described in
21 section 499B(b)(2)(B)(i), to carry out this sub-
22 section \$150,000,000.

1 **“SEC. 499G-3. PATENTING AND LICENSING INCENTIVES.**

2 “(a) IN GENERAL.—The OTT shall make every effort
3 to increase licensing throughput in order to stimulate the
4 availability of useful products for patients.

5 “(b) INCENTIVES.—The OTT shall develop incentives
6 that create private sector, financial, commercial, and aca-
7 demic interest in the National Institutes of Health’s intel-
8 lectual property portfolio, which incentives may include
9 the following:

10 “(1) The patent extension of National Insti-
11 tutes of Health’s health patents, in which there is an
12 extension of the time during which the licensee has
13 exclusive right to the intellectual property.

14 “(2) The patent restoration of National Insti-
15 tutes of Health’s health patents, in which there is
16 restoration of the full patent life, or another agreed
17 upon term, of a technology to the licensee from the
18 time of Food and Drug Administration passage or
19 other agreed upon milestone.

20 “(3) Partnering options, which are options to
21 pursue exclusive and nonexclusive licensing to 1 or
22 more partners in the government, industrial, or aca-
23 demic sectors.

24 “(c) CUSTOMIZED MODELS.—The Director of Cures
25 shall encourage the OTT to cultivate customized models

1 for contracts that fulfill the needs of industry and the pub-
 2 lic.

3 **“SEC. 499G–4. TRANSLATIONAL RESEARCHER DEVELOP-**
 4 **MENT.**

5 “(a) IN GENERAL.—The Director of Cures shall over-
 6 see the development of a curriculum for internships in
 7 interdisciplinary research that will encompass rotations
 8 through multiple institutes and centers of the National In-
 9 stitutes of Health (including the National Library of Med-
 10 icine), the clinical trial design process, and other related
 11 disciplines with an emphasis on practical experience.

12 “(b) TUITION GRANTS.—The Director of Cures shall
 13 award tuition grants for extramural interdisciplinary re-
 14 search programs.

15 “(c) TRAINING.—The Center shall train interdiscipli-
 16 nary scientists in the science and art of risk analysis and
 17 mapping through a program of internships and fellow-
 18 ships.

19 **“SEC. 499G–5. TRANSLATIONAL RESEARCH TRAINING PRO-**
 20 **GRAM.**

21 “The Director of NIH shall ensure that each institute
 22 and center of the National Institutes of Health has estab-
 23 lished, or contracted for the establishment of, a
 24 translational research training program at the institute or
 25 center.

1 **“Subpart 6—Developing Information Systems**

2 **“SEC. 499H. ADVANCING NATIONAL HEALTH INFORMATION**
 3 **INFRASTRUCTURE.**

4 “(a) GENOMIC DATA.—

5 “(1) IN GENERAL.—The National Center for
 6 Biotechnology Information of the National Library
 7 of Medicine of the National Institutes of Health
 8 shall develop new computational methods to aid in
 9 the processing of genomic data by novice and experi-
 10 enced researchers.

11 “(2) AUTHORIZATION OF APPROPRIATIONS.—

12 There is authorized to be appropriated, from the ac-
 13 celeration fund of the Director of Cures described in
 14 section 499B(b)(2)(B)(i), to carry out paragraph (1)
 15 \$8,000,000, of which—

16 “(A) \$2,500,000 is authorized to be appro-
 17 priated to support the program’s computational
 18 infrastructure; and

19 “(B) \$5,500,000 is authorized to be appro-
 20 priated for hiring biologists and computer sci-
 21 entists who are trained in bioinformatics.

22 “(b) DATABASE.—The Secretary, acting through the
 23 Director of NIH, shall undertake, in collaboration with the
 24 National Library of Medicine of the National Institutes
 25 of Health, construction of a clinical study registry and re-

1 sults database that may expand upon the National Library
 2 of Medicine’s information system and database.

3 “(c) CLINICAL TRIAL INFORMATION.—

4 “(1) IN GENERAL.—

5 “(A) IN GENERAL.—The clinical study reg-
 6 istry and results database, described in sub-
 7 section (b), shall consist of a registry of phase
 8 III clinical trials taking place in the United
 9 States and a database of their results.

10 “(B) CLINICAL STUDY REGISTRY.—Partici-
 11 pation in the clinical study registry shall be
 12 mandatory for both public and private entities.

13 “(C) RESULTS DATABASE.—Participation
 14 in the clinical trial results database shall be
 15 mandatory for both public and private entities.
 16 The clinical trial results database shall include
 17 even negative studies, which demonstrate no
 18 therapeutic effect.

19 “(2) REGISTRY OF CLINICAL TRIALS.—The reg-
 20 istry of clinical trials shall include not less than the
 21 following:

22 “(A) The clinical trial title.

23 “(B) A description of the product under
 24 study.

25 “(C) The hypothesis to be tested.

1 “(D) The intervention.

2 “(E) The study design, methodology, dura-
3 tion, and location.

4 “(F) Participation criteria.

5 “(G) Contact information.

6 “(H) Sponsoring organization.

7 “(3) CLINICAL TRIAL RESULTS.—The database
8 of clinical trial results shall consist of not less than
9 the following:

10 “(A) The trial start date and completion
11 date.

12 “(B) A summary of the results of the trial
13 in a standard, non-promotional summary for-
14 mat.

15 “(C) Summary data tables with respect to
16 the primary and secondary outcome measures.

17 “(D) Information on the statistical signifi-
18 cance of the results and publications in peer re-
19 viewed journals relating to the trial, with, when
20 available, an electronic link to the journal arti-
21 cle.

22 “(E) A description of the process used to
23 review the results of the trial, including a state-
24 ment about whether the results have been peer

1 reviewed by reviewers independent of the trial
2 sponsor.

3 “(F) Safety data concerning the trial, in-
4 cluding a summary of all adverse events speci-
5 fying the number and type of events.

6 “(G) Reference information to the clinical
7 trial in the clinical registry.

8 “(d) REGISTRATION OF TRIALS AND REPORTING OF
9 RESULTS.—

10 “(1) WEBSITE PUBLICATION.—Each principal
11 investigator of a public clinical trial or responsible
12 person for a private clinical trial shall register phase
13 III clinical trials in accordance with paragraph (2)
14 and report phase III clinical trial results in accord-
15 ance with paragraph (2) with the National Library
16 of Medicine of the National Institutes of Health.
17 The National Library of Medicine shall make the in-
18 formation available for viewing on the Library’s
19 Website, www.clinicaltrials.gov. The National Li-
20 brary of Medicine shall electronically link each reg-
21 istered clinical trial with its database of results and
22 link each database of results with its registered clin-
23 ical trial.

24 “(2) TIMELINE OF REGISTRATION.—

1 “(A) IN GENERAL.—An entity described in
2 paragraph (1) shall register a clinical trial not
3 later than 3 months after the Food and Drug
4 Administration has approved the entity’s clin-
5 ical trial protocol and report clinical trial re-
6 sults not later than 3 months after completing
7 the clinical trial, which shall be defined as the
8 point where the specified trial duration has
9 been surpassed and the analysis of the data is
10 complete or the trial is stopped because of vital
11 positive or negative findings, or as the point de-
12 termined by the judgment of the Secretary. All
13 information submitted to the National Library
14 of Medicine shall be accurate and updated.

15 “(B) LOSS OF FUNDING.—In the case in
16 which an entity described in paragraph (1) does
17 not register a clinical trial or report on clinical
18 trial results in accordance with subparagraph
19 (A), the Secretary may—

20 “(i) not award a grant, contract, co-
21 operative agreements, or any other award
22 to the principal investigators of such entity
23 until the principal investigators comply
24 with the requirements under subparagraph
25 (A); and

1 “(ii) in the case of an entity that does
2 not receive Federal funding for the clinical
3 trial, fine the entity \$10,000 a day for a
4 sum not to exceed \$2,000,000 until the re-
5 sponsible person for the clinical trial com-
6 plies with the requirements under subpara-
7 graph (A).

8 “(C) WAIVER.—The Secretary may waive
9 the requirements of subparagraph (A) upon a
10 written request from the responsible person if
11 the Secretary determines that extraordinary cir-
12 cumstances justify the waiver and that pro-
13 viding the waiver is in the public’s interest or
14 consistent with the protection of public health.

15 **“SEC. 499H-1. PUBLIC ACCESS REQUIREMENT FOR RE-**
16 **SEARCH.**

17 “(a) IN GENERAL.—The Secretary shall require all
18 funded investigators, whether direct employees of the De-
19 partment of Health and Human Services or recipients of
20 grants, contracts, or other support of the National Insti-
21 tutes of Health, the Centers for Disease Control and Pre-
22 vention, or the Agency for Healthcare Research and Qual-
23 ity, to submit to the National Library of Medicine of the
24 National Institutes of Health (referred to in this section
25 as the ‘National Library of Medicine’), upon acceptance

1 for publication in a journal or other publication included
 2 in the PubMed directory, final manuscripts resulting from
 3 research in which direct costs are supported in whole or
 4 in part by the National Institutes of Health, the Centers
 5 for Disease Control and Prevention, or the Agency for
 6 Healthcare Research and Quality.

7 “(b) PUBLIC AVAILABILITY.—

8 “(1) IN GENERAL.—The National Library of
 9 Medicine shall include all such manuscripts de-
 10 scribed in subsection (a), after peer review, for dis-
 11 play in the National Library of Medicine’s digital li-
 12 brary archive, PubMed Central. The copyright hold-
 13 er of a manuscript described in subsection (a) may
 14 request the author’s manuscript be replaced with
 15 final published text.

16 “(2) TIMELINE.—A manuscript described in
 17 subsection (a) shall become publicly available on the
 18 Internet through PubMed Central not later than 6
 19 months after the date of publication of the manu-
 20 script.

21 “(3) LOSS OF FUNDING FOR FAILURE TO SUB-
 22 MIT ON TIME.—Failure to submit required informa-
 23 tion under this section to the National Library of
 24 Medicine within 6 months of the date of publication
 25 of the manuscript involved shall be considered by the

1 Secretary in the context of grant compliance review
 2 and may result in the loss of public funding for the
 3 investigators involved as determined appropriate by
 4 the agency involved.

5 **“SEC. 499H-2. INFORMATICS TRAINING AND WORKFORCE**
 6 **DEVELOPMENT.**

7 “(a) IN GENERAL.—The Director of NIH shall de-
 8 velop a multi-faceted approach to increasing the number
 9 of persons trained in clinical bioinformatics by imple-
 10 menting appropriate programs, including the programs
 11 described in subsection (b).

12 “(b) PROGRAMS.—The programs under this sub-
 13 section are the following:

14 “(1) K–12 SCIENCE PROGRAM.—The National
 15 Library of Medicine of the National Institutes of
 16 Health shall develop with the National Science
 17 Foundation a kindergarten through grade 12 clinical
 18 informatics education curriculum that shall include
 19 an assessment component. The National Library of
 20 Medicine shall award not more than 500 schools
 21 each \$30,000 to implement the curriculum.

22 “(2) UNDERGRADUATE DEGREE PROGRAMS IN
 23 BIOINFORMATICS.—The National Library of Medi-
 24 cine of the National Institutes of Health shall—

1 “(A) award grants to academic health cen-
2 ters and graduate training programs to collabo-
3 rate with an undergraduate institution of high-
4 er education’s department of biology, chemistry,
5 or computer science to develop curricula leading
6 to a bachelor’s degree in bioinformatics; and

7 “(B) encourage grantees to form an inter-
8 institutional consortium.

9 “(3) INCREASING THE NUMBER OF NIH
10 BIOINFORMATICS GRADUATE TRAINING PRO-
11 GRAMS.—The National Library of Medicine of the
12 National Institutes of Health shall increase the
13 number of bioinformatics graduate training pro-
14 grams through funding existing graduate training
15 programs of the National Institutes of Health to
16 meet the expanding needs for training and outreach
17 to the biomedical community. The programs shall
18 focus on the skills needed to apply bioinformatics
19 methods specifically to problems of human health
20 and disease. The Director of NIH shall hire 12 indi-
21 viduals with a doctorate in molecular biology and ex-
22 pertise in training and developing educational pro-
23 grams to assist in carrying out the programs under
24 this paragraph.

1 “(4) CENTERS OF EXCELLENCE IN CLINICAL
 2 BIOINFORMATICS.—The National Library of Medi-
 3 cine of the National Institutes of Health, through
 4 the Center, shall establish Centers of Excellence in
 5 Clinical Bioinformatics that shall have state-of-the-
 6 art computational methods and tools applicable to
 7 human disease prevention, diagnosis, and treatment.
 8 The Centers of Excellence in Clinical Bioinformatics
 9 shall provide graduate student and postdoctoral sup-
 10 port, through distinguished faculty, in order to con-
 11 tribute to the highest level of training in the
 12 bioinformatics workforce pipeline.

13 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
 14 is authorized to be appropriated, from the acceleration
 15 fund of the Director of Cures described in section
 16 499B(b)(2)(B)(i), to carry out this section \$50,000,000
 17 for fiscal year 2007 and each succeeding fiscal year of
 18 which—

19 “(1) \$15,000,000 is authorized to be appro-
 20 priated for fiscal year 2007 and each succeeding fis-
 21 cal year to carry out subsection (b)(1); and

22 “(2) \$2,000,000 is authorized to be appro-
 23 priated to carry out subsection (b)(3).

1 **“SEC. 499H-3. NATIONAL LIBRARY OF MEDICINE EXPAN-**
 2 **SION OF FACILITIES.**

3 “(a) SENSE OF CONGRESS.—It is the sense of Con-
 4 gress that Congress should make special effort to fund the
 5 expansion of facilities of the National Library of Medicine
 6 of the National Institutes of Health. These facilities are
 7 essential to the National Library of Medicine being able
 8 to fulfill its many informatics functions, which include pro-
 9 viding essential informational resources to scientists
 10 worldwide and advancing the underpinning of much of the
 11 National Institutes of Health conducted biomedical re-
 12 search.

13 “(b) REPORT.—The Director shall request that the
 14 Institute of Medicine of the National Academies report to
 15 Congress on the impact of not providing funding for the
 16 expansion of facilities described in subsection (a).

17 **“Subpart 7—Research Tools**

18 **“SEC. 499I. NIH RESEARCH TOOL INVENTORY.**

19 “(a) ANNUAL REVIEW.—The Director of NIH shall
 20 direct the head of each institute and center of the National
 21 Institutes of Health to perform an annual review of the
 22 institute or center’s research tool inventory for the specific
 23 purpose of enabling each institute or center to understand
 24 the research tool distribution, frequency of use, intellectual
 25 property status, and utility. Each institute and center of
 26 the National Institutes of Health shall describe in the in-

1 stitute or center’s annual review the type and quantity of
 2 research tools the institute or center desires to obtain to
 3 better fulfill the institute or center’s research and develop-
 4 ment goals.

5 “(b) DATABASE.—The Director of Cures shall—

6 “(1) enter the information obtained from the
 7 annual review under subsection (a) into an electronic
 8 research tool database; and

9 “(2) use such database to oversee the
 10 prioritization and funding of new projects to fulfill
 11 pressing needs and promising technologies.

12 **“SEC. 499I-1. EXCEPTIONS TO TOOL GUIDELINES.**

13 “The Director of Cures may advise the Office of
 14 Technology Transfer of the Center to provide exceptions
 15 to prohibitions against patenting and licensing research
 16 tools under some circumstances of customized contracts
 17 when exclusive or non-exclusive licensing provides the
 18 swiftest and most efficacious final development of an im-
 19 portant health care technology.”.

20 (b) CONFORMING AMENDMENT.—Section 401(b)(1)
 21 of the Public Health Service Act (42 U.S.C. 281(b)(1))
 22 is amended by adding at the end the following:

23 “(S) The American Center for Cures.”.

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